



8th



CDC's National Symposium

on
Biosafety

*Biosafety and Biosecurity:
A New Era
in
Laboratory Science*

January 24 - 28, 2004
Crowne Plaza Ravinia
Atlanta, Georgia

Sponsored by:



American Biological Safety Association



Make it a Point to Join Us!



Opening Reception

Be sure to join your colleagues Sunday evening from 8:00 pm to 9:30 pm for a variety of deserts and international coffees. This is a great time to reacquaint yourself with friends and colleagues.

Southern Barbecue

Wear your jeans and boots, and we'll supply the hats. Join us Tuesday evening for a Southern Barbecue, complete with Blue Grass music. This event will be conveniently located at the hotel.

Symposium At - A - Glance

Saturday, January 24, 2004

Pre-symposium Courses: 1:00 pm - 5:00 pm

Laboratory Facilities - Commissioning Nuts and Bolts

Train the Trainer: Biosafety for Security and Municipal Responders

Sunday, January 25, 2004

Pre-symposium Courses: 1:00 pm - 5:00 pm

Crisis and Emergency Risk Communication

Update on International Transport Guidelines for Infectious Substances

Best Practices from a Security Professional Perspective

Opening Reception 8:00 pm - 9:30 pm

Monday, January 26, 2004 8:00 am - 5:00 pm

Session One: Emerging Issues

Session Two: Biosecurity

Tuesday, January 27, 2004 8:00 am - 5:00 pm

Session Three: Impact of New Regulations

Session Four: Laboratory Situations

Southern Barbecue 7:00 pm - 10:00 pm

Wednesday, January 28, 2004 8:00 am - 12:00 pm

Session Five: Facility Issues for BSL-3 Laboratories

Pre-Symposium Courses Saturday, January 24, 2004

Afternoon Workshops, 1:00 PM - 5:00 PM (Select one)

Laboratory Facilities - Commissioning Nuts & Bolts

Find out why commissioning is critical to quality building performance, who is adopting it, and why it should be considered for your facility. Learn how commissioning relates to a validation effort and how it can enhance quality building performance. Study methods for planning and implementing commissioning strategies for new or existing facilities and equipment. This workshop will identify some of the key issues in a commissioning effort such as: operations and maintenance, performance, safety, security, and biocontainment implications. Examples of the testing and documentation methods that have been implemented in successful projects will also be reviewed.

Course Instructors: Dan Artiz, George Butler Associates; Gilles Tremblay, Hemisphere Engineering; Marshall Mormyluk, Hemisphere Engineering; Lee Thompson, CUH2A/Smith Carter/Hemisphere

Train the Trainer: Biosafety for Security and Municipal Responders

Today's emergency responders can choose from a variety of training opportunities on chemical and biological terrorism, but don't usually have an opportunity to learn how the scientific community safely handles these biological agents during research or vaccine production. This half-day seminar will focus on communicating the basic elements of a biosafety program for academic, research or manufacturing facilities with emergency responders (Police, Fire and EMS). It will also discuss how the biosafety professional can assist in emergency planning and response, along with the information they can provide. The Incident Command system will also be explained. This class is for Police, Fire and EMS responders and their supervisors or managers as well as safety professionals.

Course Instructors: Tom Boyle, University of Pennsylvania and Brian Petuch, Merck Research Laboratories

Sunday, January 25, 2004

Afternoon Workshops, 1:00 PM - 5:00 PM (Select one)

Crisis and Emergency Risk Communication

The purpose of this workshop is to introduce participants to communication principles and tools critical to successful communication during a public health emergency. The participant should expect to leave this course with the following understanding:

1. Why organizations must integrate effective emergency-risk and crisis communication planning and resources into overall emergency operational planning at the community, state and federal levels.
2. Nuts and bolts of crises communications planning and tools.
3. The psychology of a public health emergency and what messages the public will need from their public health professionals.
4. How local, state, and federal emergency response and recovery operations (including government and non-government organizations) should communicate among themselves and to the public and their stakeholders.

Well planned and executed emergency risk communication, fully integrated into every state of the crisis response, can give the organization the critical boost necessary to ensure limited resources are efficiently directed where truly needed and not wasted through irrational or misguided demands from stakeholders and the public.

Course Instructors: Barbara Reynolds, CDC

Update on International Transport Guidelines for Infectious Substances

Requirements for the transport of infectious agents are in a state of flux. The driving forces behind much of the changes were initiated by the activities of Linda Hume (Transport Canada) and Nicoletta Previsani (WHO) as a result of their efforts to revise the current practices for the UN Subcommittee on the Transport of Dangerous Goods. The instructors will review the significant changes that have been incorporated into the 13th revision of the UN Model Regulations. These revisions change the classification system for infectious agents for transport purposes, as well as the packaging and labeling requirements. The incorporation of these new Model Regulations into the 2005-2006 International Civil Aviation Organization's (ICAO) Technical Instructions on the Safety Transport of Dangerous Goods by Air, and the impact of both the UN and ICAO documents on US transport regulations will be discussed.

Course Instructors: Mary Cipriano, Abbott Laboratories; Linda Hume, Transport Canada; Nicoletta Previsani, World Health Organization; Eileen Edmonson, US Department of Transportation

Best Practices from a Security Professional Perspective

If you have struggled with or wish to learn more about understanding how to identify threats, the difference between threats and vulnerabilities, how they are related to creating risk, and what solutions best mitigate specific risks, this workshop is for you. Learn how to identify, assess, and prioritize assets, threats and vulnerabilities at your institute qualitatively and quantitatively. Asset, threat and vulnerability assessment are key components of the risk assessment that is used in determining how to choose measures to reduce risk to your assets. Examples of solutions that have been successfully implemented, and procedural and operational countermeasures will be reviewed. The class will work in groups to apply this information to a "typical" institute and discuss their analysis and solutions.

Course Instructors: Barbara Johnson, PhD, Science Applications International Corporation and Edwin Taylor, Biosecurity Consultant

Monday, January 26, 2004

8:30 *Welcome and Introductions*

Session One: Emerging Issues

Session Moderator: Janet Nicholson, PhD, NCID, CDC

8:45

NIAID's Biodefense Research Efforts and Biocontainment Laboratories

Ernest T. Takafuji, MD, MPH, DMID/NIID/NIH

Since the fall of 2001, the National Institute of Allergy and Infectious Diseases (NIAID) has greatly accelerated its biodefense research activities to include efforts that will result in an expansion of biodefense research infrastructure capabilities in the nation. This presentation will describe the NIH efforts with establishment of Centers of Excellence in Biodefense Research and Emerging Infections, and the planned construction of biosafety level 3 and 4 facilities, to support the intramural and extramural efforts.

9:45 *Break*

10:15

Biosafety in the State Public Health Laboratory

Norman Crouch, PhD, Minnesota Department of Health

This presentation will discuss issues of biosafety and biosecurity addressed by state public health laboratories. The participants will be informed about the expected role these public health laboratories play in detecting and investigating bioterrorism agents and emerging infectious diseases. In addition, they will become aware of the challenges faced by these laboratories in handling undefined specimens and samples that could be infectious, toxic, or radioactive. Facilities, procedures, and training in place to assure biosafety and biosecurity in these laboratories will be described.

11:15

Communicating in a Crisis: The Art, the Science, and the Consequences if Done Wrong

Barbara Reynolds, CDC

Effective communication is a "resource multiplier" during a crisis, disaster or emergency. Many of the expected negative individual and community behaviors can be mitigated with effective emergency risk communication. Risk communication is a reasoned and mature communication approach to the selection of message, messenger and method of delivery. Emergency risk communication empowers the public's decision making and advances a behavior that allows for rapid and efficient recovery from the event.

12:15 *Lunch*

Session Two: Biosecurity

Session Moderator: Mario Morales, CDC

1:30

Biosecurity Considerations

Richard Kibbey, LTC, Science Applications International Corporation

This presentation will provide an introduction to biosecurity techniques, tactics, and procedures. Various levels of implementing security will be discussed. Security programs have several elements that need to be considered. Those elements include security measures (such as access control and human reliability), security equipment (such as protective lighting, camera systems, intrusion detection devices), and security procedures (equates to the level of security employed). The equipment coupled with security measures and procedures constitute the "Security Program". The objective of this presentation is to provide information regarding how a viable program controls entry to an area and protects select agents by successfully limiting unauthorized persons from gaining access to an area or materials and reduces the vulnerability to insider tampering.

2:30

Challenges and Solutions of Biosecurity in Academia

David Silberman, PhD, Stanford University

Beginning with a brief historical perspective on security in academic laboratories, this presentation will trace the evolution of security measures and the rationale(s) behind them. Consequences, both intended and unintended will be explored. Impacts on the hiring of faculty and the selection (and de-selection) of graduate students and post doctoral fellows as well as visiting scholars will be discussed. The presentation will also address how funding might influence research direction both nationally and at specific institutions. Concerns about publishing, attending conferences, transferring biological and chemical samples, discussions with colleagues, peer review of manuscripts, and research strategies will also be considered. In addition, the moral and ethical issues for individual researchers and institutions will be addressed.

3:30 *Break*

4:00

Threat, Vulnerability & Risk Assessment in Security Planning

Edwin Taylor, Consultant

Participants will be introduced to the methodologies that are used in the determination and quantification of threats to programs and how program vulnerabilities are determined. They will receive an outline of how risk assessment is accomplished and tailored to specific programs. The participants will learn about the involvement of organizational leadership and personnel as well as the security professional in the development and implementation of security plans.

5:00

Conclusion

The Program

Tuesday, January 27, 2004

Session Three: Impact of New Regulations
Session Moderator: Shanna Nesby-O'Dell, DVM, MPH, CDC

8:30 Regulatory Perspective
 Mark Hemphill, CDC and Denise Spenser, PhD, APHIS

The Centers for Disease Control and Prevention have published regulations (Title 42 Part 73) that establish new requirements for the possession, use, and transfer of select agents and toxins that could pose a severe threat to public health and safety. This regulation is designed to implement parts of Title II of Public Law 107-188, the "Public Health Security and Bioterrorism Preparedness and Response Act of 2002", and detail procedures for approving entities and individuals with access to a select agent or toxin. This presentation will provide an overview of this new regulation. Participants will learn 1) the legislative history of regulating biological agents and toxins; 2) understand the general requirements of the new Select Agent Rule, including exemptions and exclusions from the Rule, and 3) the current status of implementing this regulation.

9:30 Break

10:00 The CDC Select Agent Program Entity Inspection
 James Blaine, PhD, Constella Health Sciences and Kari Granier, USDA/APHIS/VS-South Carolina

The CDC Select Agent Program inspection of an entity is a three-phase process consisting of preparation for the inspection, the inspection and the response to the results of the inspection. Each phase of the process will be described from the perspective of the CDC inspector and from the perspective of the Responsible Official (RO) representing the entity. The objective of this presentation is to introduce to entity officials, subject to an inspection by the CDC Select Agent Program, the inspection process: how to prepare for the inspection, what to expect during the inspection, and what to do after the inspection.

11:00 Select Agent and Security Response
 Alan Sosebee, FBI

12:00 Lunch

Session Four: Laboratory Situations
Session Moderator: Barbara Johnson, PhD, Science Applications International Corporation

1:15 Concurrent Sessions
A. The National Laboratory Response Network: A Template for Preparedness
 Mike Miller, PhD, CDC

The objectives of this presentation are to describe the structure and function of the Laboratory Response Network (LRN); list the contact of the LRN for your state; explain how the LRN is prepared to respond to public health emergencies; and define the role of sentinel labs vs. reference labs in the LRN.

B. Veterinary Labs - Representative from USDA APHIS Invited

C. Biosecurity: An Academic/Research Community Paradigm Shift
 Cecil Smith, PhD, Ohio State University

Implementation of the Public Health Security and Bioterrorism Preparedness Act of 2002 forced Ohio State University to identify key responsibilities for biosecurity. Two principal issues came into immediate focus: 1) defining the difference between biosafety and biosecurity and 2) utilizing existing institutional administrative infrastructure to develop and implement an action plan. The Office of Research and the Office of Environmental Health and Safety became the principal stakeholders for assuring compliance and facilitating the overall process. It quickly became apparent that the climate fostering academic/research freedom was in direct conflict with regulatory mandates relating to select agents. Senior management and the research community needed a paradigm shift. Current biosecurity implications include: 1) changes in the research risk management process relating to new research and existing research; 2) development of an institutional "biosecurity matrix" consistent with regulatory mandates and institutional risk management policies; 3) understanding the key elements of risk/threat assessment, material accountability, physical security, data security, personnel security, agent transfer, emergency response/preparedness and risk communication; and 4) educating management and the research community.

D. Industry Perspective on Biosecurity
 Christina Thompson, Biosafety Consultant

The 1997 "Select Agent" rule and the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 have caused pharmaceutical and biotechnology companies to address new challenges. It has become imperative to assess threats and vulnerabilities from a number of perspectives. All facilities possessing, working with, storing, or transporting select agent pathogens and toxins have been required to increase security concerning those agents and their facilities and personnel in general. It has been necessary to form cross-functional teams of many stakeholders in companies to address biosecurity. This interactive session will cover development of biosecurity plans, biosecurity program elements, coordinated effort among major stakeholders, and the role of the biosafety professional in biosecurity planning and implementation. Participants will be encouraged to share their organization's experiences.

The Program

3:00 *Break*

3:30

Hot Topics and Roundtable Discussion

Stefan Wagener, PhD, Canadian Science Center for Human and Animal Health, Discussion Leader

A. 5th Edition of BMBL

The Centers for Disease Control and Prevention and the National Institutes of Health have initiated a collaborative project to revise the 4th Edition of BMBL. The planned publication date of the 5th Edition is April 2005. This discussion will review the history of the BMBL and describe the process for writing the new edition. In addition, the presenters will encourage conference participants to join in this collaborative initiative and help ensure that both laboratory directors and biosafety professionals will recognize the next edition as an authoritative reference on biosafety for the contemporary microbiological and biomedical laboratory.

Part I: History of the BMBL

Emmett Barkley, PhD, Director of Laboratory Safety, Howard Hughes Medical Institute and
Jonathan Richmond, PhD, Consultant

Part II: Roundtable Discussion

Shanna Nesby-O'Dell, DVM, MPH, CDC

B. Late-Breakers

5:00 *Conclusion*

Wednesday, January 28, 2004

Session Five: Facility Issues for BSL-3 Laboratories

Session Moderator: Jon Crane, AIA, CUH2A

8:30

Security Issues Related to High Containment Facilities

Leslie Gartner, AIA, Smith Carter

Security goals of high containment facilities include protection of the facility, protection of its occupants, and protection and integrity of the agents. A complete security program to achieve these goals needs to address the who (personnel), the how (operation protocols) and the what (physical security solutions). Discussion will focus on physical security solutions to meet the goals of a security plan. The issues of the physical security zones of the site, building, and laboratory will be reviewed and the inter-relationships outlined. The ways in which facility design and security devices are utilized to create a secure facility and provide monitoring and surveillance for containment facilities is evolving to meet new GSA Security Design Guidelines and the Select Agent Act will be addressed

9:30 *Break*

10:00

Retrofitting/Upgrading Biocontainment Laboratories

Bill Stratton, AIA & Yuri Yokel, AIA, LSY Architects

Conversion of existing space into functional laboratories and animal facilities presents many unique challenges not encountered in new construction. These challenges are even more severe when biocontainment design is also an issue. This presentation will focus on the specific challenges of renovating for biocontainment research facilities and the many decisions and compromises that must be addressed to achieve a successful project. Topics covered will include planning strategies, infrastructure issues, structural limitations, equipment selection, security issues, phasing concerns, finishes, and cost estimation.

11:00

New Concepts in Containment Laboratory Design

Jon Crane, AIA, CUH2A

The need for containment laboratories has driven new thinking in both the design and delivery of these facilities. This presentation will cover the critical requirements in designing containment laboratories and how they can be achieved using new methodologies. Issues such as modular design, convertibility, incorporation of advanced technologies and other new approaches will be explored. The presentation will focus on the issues surrounding BSL-3 containment.

12:00 *Concluding Remarks*

Hotel Information

The Crowne Plaza Ravinia is conveniently located in the heart of Atlanta's Perimeter Center, across the street from the Perimeter Mall. It is surrounded by ten acres of lush Japanese gardens containing walking trails.

Amenities include: complimentary, on-site fitness center, indoor pool, outdoor jacuzzi, tennis/basketball courts, three story atrium lobby, piano lounge and concierge service.

A block of rooms has been reserved at the special rate of \$112 for both single and double rooms. To make reservations call 800-554-0055 or call the hotel direct at 770-395-7700. Please indicate that you will be attending the CDC Biosafety Symposium. **Reservations must be received by January 7th, 2004.**

Registration Form

Registration Form

To register, mail completed form with check, or fax credit card payment to:
Eagleson Institute, P.O. Box 954, Sanford, ME 04073
207.490.1076; Fax: 207.324.3869; email: eagleson@eagleson.org

Participant's Name(s) _____

Company Name _____

Title(s) _____ Department _____

Address _____

City _____ State _____ Zip Code _____

Phone _____ Fax _____

Email _____

Symposium Fees

Symposium fees include Opening Reception, Tuesday Night Dinner, Attendance at Symposium Sessions, Lunch on Monday and Tuesday, and Symposium Proceedings.

FEES	By Dec 15	After Dec 15	Amt Enclosed
Symposium	\$595	\$645	\$ _____
Monday Lunch - Guest	\$30	\$30	\$ _____
Tuesday Lunch - Guest	\$30	\$30	\$ _____
Tuesday Night Dinner - Guest	\$60	\$60	\$ _____

If you or anyone in your party requires special needs, please check here ☐

PRE-SYMPOSIUM COURSES

Saturday - Select One: \$75 \$ _____
☐ Laboratory Facilities - Commissioning Nuts and Bolts
☐ Train the Trainer: Biosafety for Security and Municipal Responders

Sunday - Select One: \$75 \$ _____
☐ Crisis and Emergency Risk Communication
☐ Update on International Transport Guidelines for Infectious Substances
☐ Best Practices from a Security Professional Perspective

PAYMENT INFORMATION

TOTAL DUE \$ _____

Check enclosed (Please make check payable to Eagleson Institute/CDC National Symposium. US Funds only.)

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CANCELLATION & REFUND POLICY

Individuals who cancel on or before January 9, 2004, are entitled to a full refund less \$50 service fee. No refunds will be given after January 9, 2004. Notification of cancellation must be received **in writing**, and refunds will be issued after February 1, 2004. Substitutions for a registered attendee may be made at any time.

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